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| 10/559,373 | 02/07/2006 | Nobuaki Sumiyoshi | 2005_1741A | 3630 |
| 513 7590 08/21/2009 WENDEROTH, LIND & PONACK, L.L.P. 1030 15th Street, N.W., Suite 400 East Washington, DC 20005-1503 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/559,373

Applicant(s)

SUMIYOSHI ET AL.

Examiner

TIGABU KASSA

Art Unit

1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to the amendment filed July 23, 2009. Claims 1-23 are currently pending. Claims 16-23 are under consideration in the instant office action. Claims 1-15 are cancelled. Applicant's amendment has necessitated a new ground of rejection. Accordingly, this Action is FINAL. Receipt and consideration of Applicant's amended claim set, and remarks/arguments submitted on 07/23/09 and 05/22/09 are acknowledged.

Withdrawn rejections:

Applicant's amendments and arguments filed on 07/23/09 and 05/22/09 are acknowledged and have been fully considered. All rejections applied in the previous office action are hereby withdrawn as a result of applicants claim amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

Claims 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Segers et al. (US Patent 5383324) in view of Nakamura et al (US Patent 6867193).

Applicant Claims

Applicant claims in instant claim 16 an aseptic combination preparation to be mixed at the time of use by opening a partition wall which separates two or more chambers of a container comprising a first solution containing a potassium salt in a first chamber and a second solution containing a potassium salt in a second chamber, wherein the first solution and the second solution each have the same potassium salt and each have a potassium ion concentration of about 2 to 40 mEq/L. Instant claim 17 recites the preparation of claim 16 wherein the first solution further contains a sodium salt, a sugar and/or a bicarbonate salt. Instant claim 18 recites the preparation of claim 16, wherein the container is a plastic container. Instant claim 19 recites an aseptic combination preparation to be mixed at the time of use by opening a partition wall which

separates two or more separate chambers of a container comprising a first solution containing at least one medicinal selected from the list recited in the claim in a first chamber and a second solution containing at least one medicinal selected from the list recited in the claim in a second chamber, wherein the first solution and the second solution each have the same medicinal ingredient and each has an osmotic pressure in the range of about 1 to 3 relative to physiological saline. Instant claim 20 recites the aseptic combination preparation of claim 19, wherein the osmotic pressure ratio is about 1 relative to physiological saline. Instant claim 19 recites the preparation of claim 19, wherein the container is a plastic container. Instant claim 22 recites an aseptic combination preparation to be mixed at the time of use by opening a partition wall which separates two or more separate chambers of a container comprising a first solution containing at least one medicinal ingredient in a first chamber and a second solution containing at least one medicinal ingredient in a second chamber, wherein the first solution and the second solution each have the same medicinal ingredient. Instant claim 23 recites the aseptic combination preparation of claim 16, wherein the second solution further contains a sodium salt, a sugar and/or a bicarbonate salt.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Segers et al. teach a system designed to be used for any medical procedure requiring bicarbonate, and especially for peritoneal dialysis comprising a container with two chambers (see Figure 4). Segers et al. teach the chambers as follows (column 7, lines 19-26):

upper chamber 44 and a lower chamber 46.
In an embodiment, the multi-chamber container 42
has a frangible seal 48 between the upper chamber 44 20
and the lower chamber 46. Opening the frangible seal 48
provides fluid communication between the upper chamber
44 and the lower chamber 46. The multi-chamber 42
houses at least two non-compatible solutions that after
mixture will result in a ready-to-use dialysis solution. 25
An example of the multi-chambered container 42 is set

Segers et al. teach, for example, in an embodiment, when the solution contained in the upper chamber 44 is mixed with the solution contained in the lower chamber 46, the subsequent peritoneal dialysis solution has the following composition: 15.0 to about 45.0 (mmol/L) bicarbonate; 90.0 to about 110.0 (mmol/L) chloride; **90.0 to 142.0 (mmol/L) sodium**; 0.0 to about 2.0 (mmol/L) calcium; 0.0 to about 1.0 (mmol/L) magnesium; **0.0 to about 3.0 (mmol/L) potassium**; 0.0 to about 4.0% amino acids; **0.0 to about 4.0% peptides**; 0.0 to about 4.0% glycerol; **0.0 to about 5.0% dextrose**; and **0.0 to about 10.0% dextrose polymers**. Segers et al. also teach that in a preferred embodiment, the **upper chamber 44** can further include sodium chloride, **potassium chloride**, dextrose and dextrose polymers. Likewise, the **lower chamber 46** can further include sodium chloride, **potassium chloride**, amino acids, peptides and glycerol (column 7, lines 37-40).

*Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)*

Segers et al. do not teach an osmotic pressure ratio of about 1 to 3. Segers et al. is also silent whether the material is plastic or not. These deficiencies are cured by the teaching of Nakamura et al.

Nakamura et al teach a preparation contained in a plastic bag with two chambers which are separated by a seal which can be opened in order to mix the contents of the two chambers. One chamber contains a solution of amino acids and the other contains albumin (column 4, lines 18-36). In example 1, the osmotic pressure ratio between the amino acid and the albumin containing solutions was 2.8-3.3 (column 5, lines 8-14).

***Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)***

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the instant invention to ensure that the osmotic pressure ratio between the two solutions because Nakamura et al. teach an osmotic pressure ratio of 2.8-3.3 between two solutions of a medicinal preparation contained in adjacent chambers until mixing just prior to use. An ordinary skilled artisan would have been motivated to adjust the osmotic pressure of the solutions because the osmolality of medicinal preparations is important for the safety and efficacy of the preparation. Moreover, the instant specification points out that the administration of solutions of the incorrect osmolality due to medical error is already a well known medical problem. An ordinary skilled artisan would have had a reasonable expectation of success upon combination of the prior art teachings, because both Segers et al. and Nakamura et al. teach medicinal preparations which contain for example amino acids contained in two or more adjacent chambers which are mixed just prior to use.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). Therefore, the invention would have been *prima facie* obvious to

one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Claims 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veech (US Patent 5,200,200, IDS reference) in view of Nakamura et al (US Patent 6867193).

Applicant Claims

Applicant claims in instant claim 16 recites an aseptic combination preparation to be mixed at the time of use by opening a partition wall which separates two or more separate chambers of a container comprising a first solution containing a potassium salt in a first chamber and a second solution containing a potassium salt in a second chamber, wherein the first solution and the second solution each have the same potassium salt and each have a potassium ion concentration of about 2 to 40 mEq/L. Instant claim 17 recites the preparation of claim 16 wherein the first solution further contains a sodium salt, a sugar and/or a bicarbonate salt. Instant claim 18 recites the preparation of claim 16, wherein the container is a plastic container. Instant claim 19 recites an aseptic combination preparation to be mixed at the time of use by opening a partition wall which separates two or more separate chambers of a container comprising a first solution containing at least one medicinal selected from the list recited in the claim in a first chamber and a second solution containing at least one medicinal selected from the list recited in the claim in a second chamber, wherein the first solution and the second solution each have the same medicinal ingredient and each has an osmotic pressure in the range of about 1 to 3 relative to physiological saline. Instant claim 20 recites the aseptic combination preparation of claim 19, wherein the osmotic pressure ratio is about 1 relative to physiological saline. Instant claim 19

recites the preparation of claim 19, wherein the container is a plastic container. Instant claim 22 recites an aseptic combination preparation to be mixed at the time of use by opening a partition wall which separates two or more separate chambers of a container comprising a first solution containing at least one medicinal ingredient in a first chamber and a second solution containing at least one medicinal ingredient in a second chamber, wherein the first solution and the second solution each have the same medicinal ingredient. Instant claim 23 recites the aseptic combination preparation of claim 16, wherein the second solution further contains a sodium salt, a sugar and/or a bicarbonate salt.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Veech teaches the packaging of separate component compositions in individual chambers within a container wherein a passageway can be opened between the chambers just prior to use (abstract). Veech teaches a method involving the steps of charging respective first and second compositions into first and second chambers of a plastic container (column 2, lines 36-38). The container is designed such that the chambers are internally communicating while the container is still sealed so that final solution preparation is achieved under sterile conditions before use (column 2, lines 40-43). The chambers can contain, for example, redox active therapeutic aqueous compositions (column 2, lines 53-55) which is equivalent at least one medicinal ingredient. Exemplary solutions are taught by Veech in column 6, lines 11-39. Each of these solutions contains potassium ions up to 5 mM/L which is equivalent to 5 meq/L of potassium ions. The first composition (column 6, lines 16-24) contains sodium and chloride ions. The second solution in addition to the potassium ions also contains sodium, chloride and bicarbonate ions and also glucose (column 6, lines 30-39).

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Veech does not teach an osmotic pressure ratio of about 1 to 3. This deficiency is cured by the teaching of Nakamura et al.

Nakamura et al teach a preparation contained in a plastic bag with two chambers which are separated by a seal which can be opened in order to mix the contents of the two chambers. One chamber contains a solution of amino acids and the other contains albumin (column 4, lines 18-36). In example 1, the osmotic pressure ratio between the amino acid and the albumin containing solutions was 2.8-3.3 (column 5, lines 8-14).

***Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)***

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the instant invention to ensure that the osmotic pressure ratio between the two solutions because Nakamura et al. teach an osmotic pressure ratio of 2.8-3.3 between two solutions of a medicinal preparation contained in adjacent chambers until mixing just prior to use. An ordinary skilled artisan would have been motivated to adjust the osmotic pressure of the solutions because the osmolality of medicinal preparations is important for the safety and efficacy of the preparation. Moreover, the instant specification points out that the administration of solutions of the incorrect osmolality due to medical error is already a well known medical problem. An ordinary skilled artisan would have had a reasonable expectation of success upon combination of the prior art teachings, because both Veech and Nakamura et al. teach medicinal preparations contained in two or more adjacent chambers which are mixed just prior to use.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). Therefore, the invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Conclusion

Claims 16-23 are rejected. Claims 1-15 are cancelled. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa

08/18/09

/Mina Haghighatian/
Primary Examiner, Art Unit 1616